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Proponent Testimony for HB 101
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Chairman Burke, Vice Chair Beagle, Ranking Member Tavares, and members of the Health, Human Services and Medicaid, my name is Antonio Ciaccia, Director of Government & Public Affairs for the Ohio Pharmacists Association (OPA). I thank you for the opportunity to speak in favor of HB 101, a bill that passed out of the House unanimously earlier this year, and aims to tap pharmacists to ease access to epinephrine autoinjectors and to help facilitate better competition within the epinephrine autoinjector marketplace. I'd like to thank Representative Merrin for approaching our association with this innovative concept, and for seeking our input as he developed the legislation.

In summer 2016 – whether fairly or unfairly – local and national media pointed to Mylan's EpiPen as an example of drug pricing gone wrong. An important drug that many need as a means to stay alive was reaching price points that were no longer attainable to many patients.

The drug epinephrine has been on the market for decades, and today, the raw ingredients could be procured by a pharmacy for less than a dollar. Yet take those ingredients, and put them into a sophisticated autoinjector device … the list price can jump as high as $4,500.

As 10TV Columbus[1], the *Dayton Daily News*[2], the *Columbus Dispatch*[3], and several other Ohio and national media outlets[4,5] have demonstrated, a complicated prescription drug pricing model that incentivizes higher drug prices points to the need for national movement on pricing transparency and pharmacy benefit manager (PBM) reforms.

The EpiPen pricing controversy and corresponding public outcry has highlighted the need to facilitate easier patient access to epinephrine autoinjectors – both logistically and economically. Aside from the problems associated with opaque pricing gimmicks, there are other factors that may be contributing to epinephrine autoinjector prices and accessibility, and Rep. Merrin's HB 101 will tackle two specific issues.

House Bill 101 would allow pharmacists to substitute a prescribed, brand-name epinephrine autoinjector for a pharmaceutically equivalent epinephrine autoinjector. For example, if a physician prescribes EpiPen that retails around $600, under HB 101, a pharmacist could substitute a less expensive alternative, with the patient's consent, that can cost hundreds of dollars less and still meet the patient's pharmaceutical needs. This is important, as pharmacists have reported that nearly all epinephrine autoinjector prescriptions arrive at the pharmacy bearing the name "EpiPen." Today, Mylan has the only approved generic version of EpiPen, so if the prescriber writes for "EpiPen," Mylan still has the only alternative, substitutable product. Other competitor epinephrine autoinjectors – even though they are pharmaceutically equivalent to the EpiPen – cannot currently be substituted by the pharmacist, simply because those other autoinjectors are operated in a slightly different fashion.

Here's why. According to recently appointed FDA Commissioner Dr. Scott Gottlieb[6], *"One issue relates to the existing generic drug law, and FDA regulations that govern the generic approval process and the Abbreviated New Drug Application (ANDA) that a generic drug maker must file with FDA. Under the Agency's interpretation of those rules, if a patient has to be re-trained to use a generic alternative to a branded product, then the alternative product cannot bear the same labeling as the drug it seeks to copy. As a result, it can't meet the burden of the ANDA process and be approved as a generic equivalent. In other words, the generic drug can't be considered the 'same' as the branded version that it seeks to copy, and serve as a fully substitutable alternative."*

So essentially, because other epinephrine autoinjectors aren't substitutable under current law, if a physician issues a prescription for a branded epinephrine autoinjector, the pharmacist's hands are tied unless they work with the physician to get a new prescription for an alternative product. This all unnecessarily wastes the time of the physician, pharmacist, and the patient – and could take as long as 48 hours to get authorization from the doctor's office for the switch. HB 101 would allow pharmacists to exercise their professional judgment to make the necessary product switches, so long as the products are deemed pharmaceutically equivalent – and only if the patient consents to the substitution, and the pharmacist trains the patient on how to operate the substituted device.

This level of flexibility is needed on a more national scale with many types of medications, but for now, this creates a safe, competitive way forward for epinephrine in Ohio, much as Dr. Gottlieb explained in his October 24, 2016 piece in *Forbes*[6], "EpiPen shows a path to solve the bigger drug pricing challenge."

The second part of HB 101 would enable pharmacists to dispense epinephrine autoinjectors to adults 18 years of age or older, under a physician's protocol. Under the bill, the Ohio State Board of Pharmacy, with consultation of the State Medical Board of Ohio, will establish protocol requirements that govern the conditions under which pharmacists can dispense epinephrine autoinjectors to adults without a prescription.

Currently, Ohio pharmacists & pharmacy interns can dispense naloxone and administer all CDC-recommended vaccines without a prescription to patients 13 years of age and older (prescription required for ages 7 to 12), as long as they are acting within a physician protocol. HB 101 would add epinephrine autoinjectors into a similar category, thus eliminating the need to visit or contact the doctor for a new prescription every year.

As new laws took effect in 2016 to allow restaurants, swimming pools, colleges, and other public places to stock non-patient specific epinephrine for possible allergic reactions, this bill would eliminate the unnecessary step of these entities seeking out a doctor's prescription before obtaining the product to use in emergency situations, just like they use fire extinguishers and defibrillators today.

Currently, pharmacists are already empowered to administer epinephrine to patients in the event that a patient has an adverse reaction to a vaccine or long-acting injectable medication administered at the pharmacy. The training on the drug is already required for all immunizing pharmacists, and this is by no means new territory for pharmacists, as the protocol requirements for pharmacist-administered medications already governs this process for emergency situations.

Under HB 200, which was signed into law in the 131st General Assembly, among other great provisions, the new law allows a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner to issue a prescription for an epinephrine autoinjector without ever having to examine the patient for whom the prescription is issued. These guidelines are arguably more lax than the ones delineated in HB 101 for pharmacists, and allow for prescriptions to be issued for children as well – which HB 101 also avoids.

HB 200 also allowed qualified entities (workplaces, schools, restaurants, amusement parks, camps, etc.) to train and designate non-medical staff to obtain, store, and even administer epinephrine autoinjectors to persons they deem as possibly experiencing anaphylaxis. Again, there are no age restrictions mentioned for these laypersons under current Ohio law, yet those age restrictions are noted in HB 101 for pharmacists.

I'll remind members of this committee that pharmacists receive 6 to 8 years of doctorate-level training, and generally receive more pharmacology training than any other health care professional. Their educational training is specifically focused on medications and their impact on patient disease states. From my vantage point, this bill is an inch of scope for a mile of access.

Furthermore, on January 17, 2017, CMS's Center for Medicaid and CHIP Services (CMCS) issued an Informational Bulletin[7] encouraging states to expand the scope of pharmacy practice as a way of fostering immediate access to certain drugs, whether it be through protocols, collaborative agreements, or even independent prescribing. CMCS added that these practices are solely a state option, not a requirement, but stressed that they can "facilitate easier access to medically necessary and time-sensitive drugs for Medicaid beneficiaries."

All states now allow pharmacists to administer immunizations (Ohio allows all CDC-recommended vaccines to ages 7 and up); nearly all have liberalized their laws on naloxone; three states now allow pharmacists to prescribe contraception, and the state of Idaho recently enacted a law to allow pharmacists to prescribe any medication authorized by their state board of pharmacy. I say this because pharmacists have been incredibly underutilized in our health care system, and bills like HB 101 are really what I consider to be the basics of what pharmacists should be empowered to do in the future – not as a replacement for doctors or nurses; but as a complement.

For Ohioans at risk of anaphylactic shock, epinephrine delivered by an autoinjector is a medical necessity and often life-saving. However, the price and unnecessary logistical hassles have become a barrier to access and attainability. The good news is there are multiple epinephrine autoinjectors on the market and more in the pipeline. Under HB 101, consumers will have increased ability to work with pharmacists to secure the best epinephrine autoinjector at a competitive price.

I'd like to thank Representative Merrin his legislative aide Blake Springhetti for all their work on this legislation. I'd also like to thank the Ohio Council of Retail Merchants and the Ohio State Medical Association for their support, and the Ohio House of Representatives for their unanimous passage of the bill.

I thank you for your time today. I am happy to offer the Ohio Pharmacists Association's support for HB 101, and I'd welcome any questions you may have.

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